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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,629	03/19/2002	Kim Allen Heithoff	AL01071K	7226

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 10/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/088,629	Heithoff
Examiner	**Art Unit**
Phyllis G. Spivack	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 9-55 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 9-55 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicant's Preliminary Amendment filed March 19, 2003, Paper No. 3, is acknowledged. Priority is established, claims 1-8 are canceled and new claims 9-55 are presented which represent all of the claims now under consideration.

The undersigned Examiner supports the goal of the Office to advance prosecution as expediently as is reasonably possible. Cooperation is requested with respect to the timely submission of any references deemed pertinent to the present application along with Form PTO-1449.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz, R.M., Pediatric Asthma, Allergy & Immunology, in view of Handley et al., U.S. Patent 5,900,421.

Katz teaches the administration of loratadine to students with seasonal allergic rhinitis who may experience decreased academic performance and productivity. Mast cell histamine is known to be a mediator in immediate hypersensitivity reactions evoking mucous secretion, vasodilation, increased vascular permeability, pruritus and sneezing. Histamine is synthesized and stored in secretory granules of mast cells located throughout the body, such as the skin, such that atopic dermatitus and/or urticaria may result. See page 96, the second paragraph under *Assessment of*

sedation where various dosages, as required by claims 10-13, 16-19, 23-26, 29-32, 34-37, 39-42, 46-49, 53 and 55, are disclosed, as well as the first paragraph on page 97. Following oral administration, loratadine is rapidly metabolized to desoratadine, an active metabolite. The claims differ in that loratadine is the antihistamine discussed, not the metabolite desloratadine. However, Handley provides motivation to administer desloratadine in place of loratadine. See column 2, lines 26-33 and lines 52-56. Loratadine has been shown to cause severe cardiologic adverse effects, and to display a greater potential for drug interactions where loratadine is given with drugs known to inhibit cytochrome P450. Accordingly, one skilled in the allergy art would have been motivated to administer the metabolite desloratadine to accelerate a person's return to workplace productivity in view of the combined teachings of Katz and Handley. Such would have been obvious in the absence of evidence to the contrary because the active metabolite, descarboethoxyloratadine or desloratadine, was known in the prior art at the time of the present invention as a selective, non-sedating H_1 receptor antagonist. Because loratadine administration results in no clinically significant CNS activity and does not result in impaired performance in tasks involving motor function, this antihistamine is shown by Katz to be preferred over first generation antihistamines in patients who must remain alert. Further, Handley teaches the avoidance of adverse side effects associated with loratadine. Thus, it would have been reasonable to expect these parameters to lead to the ability of substantially returning to work-related performance and/or workplace productivity for a person suffering from an allergic and/or inflammatory condition of the skin or airway passages, as atopic

dermatitis and/or urticaria, or, seasonal and/or perennial allergic rhinitis, to the person's baseline work-related performance or workplace productivity following desloratadine administration.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

September 30, 2003

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER